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CARRIER MEDIUM FOR ANALYZING A SUBSTANCE

BACKGROUND OF THE INVENTION

The present invention relates in general to the field of testing for various physical conditions, and in particular to a carrier medium for analyzing an analyte.

Carrier media are known which are used for testing an analyte for a specific condition. To this end, a biological or chemical substance is applied to the carrier medium, the substance either reacting or not reacting upon contact with the analyte substance being tested, depending on the presence or absence of a corresponding specific physical condition. Typically, the reaction is manifested by a color change in the carrier medium. Known carrier media include, for example, those which, when they come in contact with a liquid, change color in response to the pH of the liquid, or carrier media which, upon contact with urine, indicate whether or not a pregnancy is present. Carrier media coated with an antibody are able to verify through a color reaction whether or not the associated viruses are present in the blood of a patient.

A disadvantage of carrier media of this type is that an analyte may be tested only for a single condition per carrier medium. If a number of analyses for different conditions are to be made on the analyte, a time-consuming and costly analysis at a physician's office is required involving multiple carrier media and a large quantity of the analyte such as blood or urine.

What is needed is a single carrier medium that is suitable for multiple analyses, thereby offering a method of analysis that is convenient, saves time and expense, and requires smaller quantities of biological or chemical material substances and analytes to carry out the multiple analyses.

SUMMARY OF THE INVENTION

In a carrier medium having at least two defined regions, biological and/or chemical substances are applied to the regions of the carrier medium for analyzing an analyte. The carrier medium is also provided with a code that indicates which biological and/or chemical substance is located in which defined region. The application of multiple biological and/or chemical substances to one carrier medium enables multiple analyses to be performed simultaneously on the analyte. This approach reduces the required quantities of the biological and/or chemical substances needed to perform the desired analyses of the analyte. The carrier medium itself does not reveal which biological and/or chemical substance is located in which region; this information may instead be provided by the code.

Several hundred biological and/or chemical substances may be applied in a corresponding number of defined regions on the medium. As a result, several hundred analyses may be performed simultaneously on an analyte such as blood or urine, using a single carrier medium, thereby saving considerable time and expense.

The biological and/or chemical substances may be arranged differently within the defined regions on two different carrier media. As a result, it may not be possible to draw conclusions from the arrangement of the biological and/or chemical substances on one carrier medium about the corresponding arrangement of biological and/or chemical substances on a second carrier medium. It is by reading the code on a particular carrier medium that it may be possible to determine which biological and/or chemical substance is located in which region on that particular medium.

The defined regions may be arranged differently on two different carrier media. As a result, it may not be possible to draw conclusions from the arrangement of the defined regions on one carrier medium about the arrangement of the defined regions on a second carrier medium. This provides an

additional means of encoding.

A temperature sensor for detecting ambient temperature may be provided on the carrier medium to record any storage of the carrier media at excessively high or low temperatures.

The code may be a barcode, a numerical code, or an alphanumeric code, or the code may be provided by the arrangement of the defined regions on the carrier medium. This last implementation variant for the code may be useful when no space is provided on the carrier medium for a barcode or other type of discrete code.

The code may provide information to a device reading the carrier medium as to how the device should read the defined regions. For example, if certain biological and/or chemical substances respond in a completely different wavelength region than other biological and/or chemical substances, the code may contain this information and instruct the reading device to set specific detectors for the reading in accordance with the expected wavelengths to be detected.

The code may contain information about the expiration date of the carrier medium. After specific storage periods, certain biological and/or chemical substances react to form different substances and, as a result, may no longer be used for the designated analyses. As such, the code may pass on the appropriate information to a device reading the carrier media such that a corresponding warning may be issued by the reading device if a carrier medium is used after the expiration date.

The code may contain information about the storage of the carrier medium from the time of manufacture to the time the carrier medium was used. For example, certain biological and/or chemical substances typically may not be stored above or below specific temperatures, as otherwise certain undesirable reactions occur. Thus, the carrier medium may contain means for detecting the ambient temperature whereby if certain temperatures are exceeded, either on the high side or low side, these variations are stored in the code. If such a carrier medium is nonetheless used for an

analysis, the reading device is able to detect based on the code that the carrier medium has not been stored according to specification and issue a warning to this effect.

The carrier medium may be composed of a film strip, glass carrier, or paper.

The biological and/or chemical substances may be DNA, RNA, proteins, or antibodies. As a result, analyses may be performed focusing on bacteria or viruses.

A method for producing the carrier media comprises the following steps:

a. producing a set of carrier media having a first arrangement of the defined regions and/or a first arrangement of the biological and/or chemical substances within the defined regions;

b. assigning a different code to each of these carrier media in the set;

c. storing the arrangement of the defined regions and/or the arrangement of the biological and/or chemical substances within the defined regions of the carrier media along with the associated codes;

d. selecting a second arrangement of the defined regions, and/or of the biological and/or chemical substances in the defined regions, that is different from the first arrangement;

e. implementing steps a through c for the second arrangement; and

f. implementing steps a through c for subsequent arrangements different from the arrangements previously used.

This production method ensures that each individual carrier medium produced receives a different code, and that the code is stored along with the associated arrangement of defined regions and/or with the arrangement of biological and/or chemical substances in the defined regions. While a certain number of carrier media are thus produced which have an identical arrangement of defined regions, and/or of biological and/or chemical substances in the defined regions, nevertheless these carrier media are differentiated by their corresponding codes, with the result that no two carrier

media identical in every respect are produced, and when two carrier media are compared it is likely not possible to detect which biological and/or chemical substance is located in which defined region.

The code may be provided by a simple numbering of the carriers. A code of this type may be the simplest means of providing the different carrier media with different codes.

The biological and/or chemical substances may be printed on the defined regions of the carrier media with a print head analogous to that used in an inkjet printing process. As a result, the carrier media may be produced in a relatively inexpensive manner, while the defined regions are able to be locally placed with high precision on the carrier media.

One set may comprise approximately 1,000 to 10,000 carrier media, and several hundred different sets may be produced. As a result, a large number of carrier media are produced whereby the carrier media are present in different forms.

One type of carrier medium may be selected from each of the various sets, and these selected carrier media may be packaged together. As such, one pack contains carrier media with different arrangements and, as a result, it may not be possible to draw conclusions from the arrangement on one carrier medium about the arrangement of a second carrier medium in the same pack. Since the various packs may be distributed throughout a given country, or are even distributed worldwide, the probability that a given user may receive carrier media having identical arrangements (although with different codes) is extremely low.

Alternatively, multiple sets of carrier media may be mixed and randomly selected for inclusion in a common pack. As such, two carrier media with identical arrangements may be included in one pack, although the probability of this occurring is relatively low given a sufficient number of different sets.

A device for reading a carrier medium has at least one optical detector per defined region.

The optical detectors detect the reactions of the biological and/or chemical substances in the defined regions when the carrier medium has been brought into a read position relative to the device.

The device may have means for acquiring and transmitting the code to an administrative center. The device itself may not be able to determine the arrangement of the carrier medium read from the code if the arrangement of the defined regions, and/or the arrangement of biological and/or chemical substances within the defined regions, along with the associated codes, are not stored within the reading device. As such, it may be necessary to transmit the code to an administrative center in which the specific arrangement corresponding to the extracted code is determined. The device itself may only be able to detect in which defined region a reaction of the biological and/or chemical substances has occurred in response to the analyte; it may not, however, be able to indicate which biological and/or chemical substance has reacted.

The optical detectors of the device may be semiconductor chips.

Means for digitizing the detected signals and/or transmitting the detected signals to the administrative center may be provided in the device so that the detected signals may undergo subsequent processing.

A method for reading a carrier medium in conjunction with the use of a device for reading the carrier medium comprises the following steps:

a. applying the analyte to the carrier medium;

b. moving the carrier medium into the read position relative to the device for reading the carrier medium;

c. transmitting the code of the carrier medium to an administrative center; and

d. within the administrative center, evaluating the code and determining the associated arrangement.

An advantage of the method for reading a carrier medium is that it provides the manufacturers of the carrier media or of the biological and/or chemical substances, and/or the medical insurance company, with a profitable accounting system. The application of several hundred different biological and/or chemical substances onto a carrier medium means that significantly smaller quantities of these substances are required. The quantities required may be reduced by a factor of between 10^6 and 10^9. An accounting system may nevertheless be needed to ensure that the production of these biological and/or chemical substances remains profitable.

The fact that such carrier media are produced in relatively large quantities, since they provide a simple test for certain diseases, bacteria or viruses, and are thus utilized frequently, does not compensate for the loss generated by the smaller required quantities. For this reason, the method of reading the carrier media may leave evaluation of the carrier media to a central administrative center. Although the carrier media and the device for reading a carrier medium may enable a person to detect reactions of the biological and/or chemical substances to the analyte, the person may not be able to correlate the detected reactions with specific biological and/or chemical substances. To accomplish this, the code may be transmitted from the device for reading a carrier medium to the administrative center at which the arrangement associated with the code may be determined. While the person may be able to determine whether or not a positive reaction of the analyte to some kind of biological and/or chemical substance has occurred, it may not be possible for the person to determine which biological and/or chemical substance is involved. To cover the cost of production of the carrier media, or of the biological and/or chemical substances, the cost of determining a given arrangement associated with a code may, for example, be accounted for in the administrative center.

However, the evaluation of the code and determination of the associated arrangement within the administrative center may be performed at no cost. As such, a fee may be charged if an analyte

has reacted positively to the biological and/or chemical substances. This approach provides a health service that may be implemented in a cost-effective and time-saving manner for the individual but which is also acceptable to the medical insurance companies and the overall healthcare system. The cost-effective availability of the carrier media enables an individual, for example, to test his/her blood or urine on a regular basis for reactions to certain biological and/or chemical substances, whereby a fee may be incurred only if a reaction has occurred; that is, if the person is ill or has a certain condition. The relevant fee or partial fee may, for example, be passed on by the administrative center to the medical insurance companies.

The administrative center may transmit instructions to the reading device as to how the optical detectors are to be set for the specific defined regions. This better ensures a high-quality read-out of the carrier medium.

The method for reading a carrier medium may comprise additional steps. For example, in a step e, the reactions of the defined regions may be detected with the optical detectors adjusted as best as possible.

In a step f, the detected signals may be transmitted to the administrative center. In a step g, the arrangement of the biological and/or chemical substances of the carrier medium, and/or the evaluation of the detected signals, may be transmitted from the administrative center to the device for reading.

In the alternative, the reactions of the defined regions may first be detected by the optical detectors of the reading device after step b, and then the detected signals may also be transmitted to the administrative center in step c. The steps related to transmitting the instructions to the reading device may thus be eliminated, although the first reading of the carrier medium may not be performed with the optical detectors adjusted as best as possible.

In the step e, the arrangement of the biological and/or chemical substances of the carrier medium and/or the evaluation of the detected signals may be transmitted from the administrative center to the reading device.

In the alternative, requests may be sent by the administrative center to set certain defined regions in accordance with the detected signals to increase the accuracy of measurement and reduce the probability of error.

A request may be sent by the administrative center, in response to certain detected signals, to read another carrier medium having additional biological and/or chemical substances different from the biological and/or chemical substances on the first carrier medium after application of the analyte. In this way, additional tests may be performed in the case of a reaction to a given biological and/or chemical substance possibly indicating the presence of a certain disease.

The detected signals and the code for the transmission from the reading device to the administrative center may be encrypted with a public key. This measure offers additional security for the data transfer while also providing to the administrative center a means for decrypting the data.

The transmission of the detected signal and code to the administrative center may be error-protection-coded. This measure provides a higher level of security for the data transfer.

These and other objects, features and advantages of the present invention will become more apparent in light of the following detailed description of preferred embodiments thereof, as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a first embodiment of a carrier medium;

FIG. 2 illustrates a second embodiment of a carrier medium;

FIGS. 3A and 3B illustrate a third embodiment of a carrier medium; and

FIG. 4 is a perspective view of a device for reading the carrier medium of FIGS. 1-3A,3B.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, there illustrated is a carrier medium 10 composed of, e.g., a rectangular film strip on which defined regions 11 are aligned on an essentially square grid 15. The carrier medium 10 may be approximately the size of a check card or credit card. A code 12 may be located on one narrow end of the carrier medium 10, the code being in the exemplary form of a numerical code. The code 12 may be located at any desired site on the carrier medium 10. A barcode or alphanumeric code may be used in place of the numerical code 10.

Biological and/or chemical substances may be applied within the defined regions 11 of carrier medium 10, whereby each of the individual defined regions 11 may contain a different biological and/or chemical substance. Several hundred defined regions 11 may be located on the carrier medium 10 such that the naked eye may not be able to detect the defined regions 11. The naked eye thus may not be able to recognize which biological and/or chemical substance has been applied to which defined region 11. The code 12 may provide information as to which substance is located in which region 11. This information may not, however, be directly accessible to the user of the carrier medium 10.

The carrier medium 10 may have a temperature sensor 17 to record the ambient temperature of the carrier medium 10. Certain biological and/or chemical substances may only be stored at certain temperatures. In the event a maximum temperature or minimum temperature has been exceeded, the biological and/or chemical substances react to form different substances, and are thus may no longer be usable for the desired test. The information as to whether or not the specified temperature range

has been maintained may be accessible from the temperature sensor 17 and may be retrieved by the device for reading the carrier medium 10.

Referring to FIG. 2, there illustrated is a second embodiment of a carrier medium 20. The carrier medium 20 may also be composed of an essentially rectangular film strip on which biological and/or chemical substances have been applied within the defined regions 21 of the film strip. Unlike FIG. 1, the defined regions 21 in FIG. 2 may not all be aligned in an essentially square grid 25. Some of the defined regions 21 may be located at the intersection points of the grid 25, whereas other defined regions 21 may deviate, either horizontally or vertically, from the intersection points of the grid 25. The biological and/or chemical substances may be arranged within the defined regions 21. However, due to the use of several hundred of the defined regions 21, the regions 21 are of correspondingly small size so that the naked eye may be unable to detect which biological and/or chemical substance is located in which of the defined regions 21. The pattern created by the deviations of defined regions 21 from the intersection points of grid 25 may represent a code indicating which biological and/or chemical substance is located in which of the defined regions 21.

In a method for producing the carrier media, not all of the carrier media may be identical. For example, FIGS. 3A and 3B illustrate two different carrier media 30 and 30', respectively, that may be made from the same production process. In the method, a set of identical carrier media may be first produced with a first arrangement of biological and/or chemical substances in defined regions 31, as illustrated in FIG. 3A. The defined regions 31 may be arranged in an essentially rectangular grid. The biological and/or chemical substances are designated in FIGS. 3A and 3B by capital letters A through I. A different biological and/or chemical substance may be located in each of defined regions 31 in FIG. 3A. The carrier medium 31 may also be equipped with a temperature sensor 37.

For simplicity, the carrier medium 30 of FIG. 3A is illustrated with nine defined regions 31.

However, the carrier medium 30 may have, for example, 500 defined regions 31 arranged in a grid defined by a 25 x 20 matrix.

In this first exemplary set of carrier media, the arrangement of the biological and/or chemical substances may be identical. However, all of the carrier media 30 in the first set of carrier media are distinguished by a code 32 which is imprinted on one of the narrower ends of carrier medium 30. For example, if code 32 is a seven-digit number, a maximum of ten million carrier media 30 could be produced with the first arrangement of biological and/or chemical substances such that each carrier medium 30 has a different code. In the present example, the first set of carrier media 30 may comprise 10,000 media which may be numbered by numerical codes 1 through 10,000. Information may be stored in the administrative center indicating that carrier media 30 with codes 1 through 10,000 have the first arrangement of biological and/or chemical substances.

In a second exemplary set of carrier media 30' illustrated in FIG. 3B, the arrangement of biological and/or chemical substances has been modified. The biological and/or chemical substance A, which in the first set of carrier media 30 in FIG. 3A in defined region 31 is located at the top left, is now located within defined region 31' in FIG. 3B at the center of the top line. The position of each the subsequent biological and/or chemical substances B-I may also be modified. This exemplary arrangement of biological and/or chemical substances within the defined regions 31' of FIG. 3B may be identical for all of the carrier media 30' of the second set of carrier media. The carrier media 30' of the second set of carrier media are similarly distinguished by a code 32' which may be imprinted on one of the narrower ends of carrier medium 30'. The codes 32' may be used for the second set of carrier media 30', and may be different from the codes 32 used with the first set of carrier media 30. For example, the second set of carrier media 30' may also have 10,000 media which are numbered with codes 10,001 through 20,000.

Each carrier medium thus receives a different code, although multiple carrier media may have an identical arrangement of biological and/or chemical substances within the defined regions. Each carrier medium produced is therefore different in that each medium has its own unique code. The number of possible different carrier media may be determined by the number of biological and/or chemical substances on the carrier medium and by the maximum number of different codes. If a carrier medium has 500 different biological and/or chemical substances, the result is 500! different arrangements for the biological and/or chemical substances, whereby in the case of a seven-digit numerical code ten million different codes may be provided for each arrangement.

To ensure that, after the production of, for example, 200 sets of carrier media with the same arrangement, carrier media having different arrangements of biological and/or chemical substances may be contained in one pack, 100 sets for example may be randomly selected from the 200 sets, and from these 100 sets one carrier medium each may be selected, after which the carrier media thus selected may be packed in one pack. The selection of the sets and carrier media may be implemented using a random number generator.

Use of the carrier media comprises applying an analyte, for example the blood or urine of a patient, to the surface of the carrier medium. Biological and/or chemical substances which may be used include DNA, RNA, proteins, and antibodies. If the analyte contains the corresponding "counterpart" to the biological and/or chemical substance, a reaction takes place which is generally manifested as a change in color of the corresponding defined region. The color changes may, for example, lie in the visible region of the spectrum, or they may also lie within the infrared or ultraviolet regions. Given that there are several hundred defined regions on one carrier medium the size of an credit card, it may not be possible for the naked eye to detect the reactions of the analyte with the biological and/or chemical substances. Thus, referring to FIG. 4, the carrier medium 30 may

be placed, after application of the analyte, into a device 50 for reading the carrier medium. The device 50 may have a drive system, analogous to a disk drive, in which carrier medium 30 is moved into the read position relative to the device 50. Once the carrier medium 30 is in the read position, optical detectors, for example semiconductor chips, are located above the individual defined regions 31, which detectors detect the color changes of defined regions 31. However, the device 50 may not be capable of assigning the detected signals to the biological and/or chemical substances A through I applied to defined regions 31 of the carrier medium 30 of FIG. 3A. For this purpose, a means may be attached to device 50 which reads code 32 of carrier medium 30 and transmits it to the administrative center.

In a first method, the detected signals for defined regions 31 are transmitted along with the code 32. The assignment of relating the code 32 to the arrangement of biological and/or chemical substances A through I within the defined regions 31 of the different carrier media 30, 30' may be stored in the administrative center. Thus, the administrative center may determine for which biological and/or chemical substances A through I a reaction has taken place with the analyte. The administrative center may then send the result back to the device 50 and, depending on the situation, may indicate whether additional carrier media, such as those with different biological and/or chemical substances, are to be analyzed. For example, if on the initially analyzed carrier medium a positive reaction has been found for a certain biological and/or chemical substance, it may be appropriate to analyze the analyte for additional biological and/or chemical substances which were not present on the first carrier medium. In addition, the administrative center may be able to instruct the device 50 reading a carrier medium as to how the optical detectors should be located in regard to the given arrangement of biological and/or chemical substances A through I. If necessary, testing may be repeated on the carrier medium 30 using the located optical detectors.

In a second method, the device 50 may first read the code 32 of the carrier medium 30 and then may send the code to the administrative center. The administrative center may determine the associated arrangement of biological and/or chemical substances A through I from the code 32 and may then instruct the device 50 as to how the optical detectors for this carrier medium 30 should be located. The device 50 may then perform the read procedure and detect the color signals emitted by defined regions 31. These may be subsequently sent to the administrative center which may determine whether, and if so which, of biological and/or chemical substances A through I have reacted with the analyte.

On the carrier medium 30, information may be provided within the code 32 about the expiration date of the carrier medium 30, which information is, for example, present as a supplementary six-digit code number attached to the seven-digit code number 32 containing the information about the arrangement of biological and/or chemical substances A through I within defined regions 31. The device 50 may read this code and issue a warning if the expiration date has already been passed.

In addition, the device 50 may read the information from temperature sensor 37 and may issue a possible warning if the specified maximum or minimum temperature has been exceeded at any time while the carrier medium 30 was stored.

Transmission of the data from the device 50 to the administrative center may proceed after the data has been encrypted using a public key. This key may be provided by the administrative center, and thus only the administrative center may be able to decrypt the data. In addition, transmission of the data may be error-protection-coded so that any transmission errors may be immediately discovered and eliminated.

To finance the production of the carrier media and, specifically, the biological and/or

chemical substances, while at the same time providing the most inexpensive possible medical screening test for any person, provision may made whereby the evaluation of the codes and determination of the associated arrangement of the carrier media may be performed at no charge within the administrative center, and a fee may be charged only if one of the biological and/or chemical substances has reacted with the analyte.

Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.

What is claimed is: